K010966

JUN - 8 2001

ALARIS™
MEDICAL SYSTEMS

510(k) SUMMARY

SUBMITTER'S NAME:

ALARIS Medical Systems, Inc.
10221 Wateridge Circle
San Diego, CA 92121-2772
(858) 458-7563
(858) 458-6223 FAX

CONTACT PERSON:

Renée L. Fluet
Principal Regulatory Affairs Specialist

DATE PREPARED: March 30, 2001

DEVICE NAME:

Proprietary Name
Medley SpO_2 Module

Common Name
Pulse Oximeter and Sensor

Classification Name
Oximeter (74DQA) (870.2700)
Cable, Transducer and Electrode (74DSA)(870.2900)

PREDICATE DEVICE:

Masimo SET® 2000 Pulse Oximeter and Accessories
K990966
Masimo SET® Radical Pulse Oximeter Accessories
K002574

DEVICE DESCRIPTION

The Medley SpO_2 Module and accessories is capable of non-invasively monitoring functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. The Medley SpO_2 Module is an additional module to the currently cleared "Medley Patient Care System" (K950419, Imed Orion Infusion Pump and Administration Sets). The SpO_2 Module features an easy-to-read LED (light emitting diode) display that presents patient data and status indicators. Additionally, an LCD (liquid crystal display) on the Programming Module shows the SpO_2, pulse rate values, and a plethysmographic waveform, the current high and low SpO_2 and pulse rate limit alarm settings, and messages as appropriate.

The Medley system consists of an SpO_2 Module, a Programming Module (PM), connecting cable, and oximetry sensors. The Medley SpO_2 Module contains a 3rd party (Masimo Corporation) manufactured board capable of monitoring functional oxygen saturation and pulse rate (K990966, Masimo SET® 2000 Pulse Oximeter and Accessories). Masimo's board contains all of the pulse oximetry algorithms used to measure saturation and pulse rate. Masimo's LNOP series of patient cables and oximetry sensors work in combination with the Medley SpO_2 Module to utilize Masimo's technology to measure functional oxygen saturation and pulse rate.

14

510(k) SUMMARY, Continued

Masimo series of LNOP sensors and accessories are cleared for market under "K990966, Masimo SET® 2000 Pulse Oximeter and Accessories" and "K002574, Masimo SET® LNOP series of Sensors and Cables" (DCIP only).

The Medley SpO_2 Module utilizes the Masimo LNOP series of oximetry sensors and are available in six configurations:

- LNOP Adt — Adult, single use sensor for >30 kg patients
- LNOP Neo — Neonatal, single use sensor for <10 kg patients
- LNOP NeoPT — Neonatal, single use sensor for <1 kg patients
- LNOP DCI — Adult, re-usable sensor for >30 kg patients
- LNOP Pdt — Pediatric / Slender Digit, single use sensor for patients between 10 and 50 kg
- LNOP DCIP — Pediatric, re-usable sensor for patients >10 kg and < 50 kg

The Masimo LNOP series of oximetry sensors measure the light absorption of blood from two LED's. Oxygen saturated blood absorbs light differently than unsaturated blood. The amount of light absorbed by the blood is used to calculate the ratio of oxygenated hemoglobin to total hemoglobin in arterial blood.

- PC Series — Patient Cables for use with the LNOP series of sensors

Masimo's PC series of connecting cables are available in one configuration and three lengths: 4 feet, 8 feet, and 12 feet.

Intended Use

The Medley SpO_2 Module and accessories is intended for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor) for adult, pediatric, and neonatal patients in hospitals and hospital-type facilities.

Summary of technological characteristics

The Medley SpO_2 Module as described in this 510(k) premarket notification and the Masimo SET® 2000 Pulse Oximeter (K990966) are similar devices. The pulse oximeter systems have the same intended use, principle of operation, technology, functionality, and performance specifications. In addition, the Medley SpO_2 Module and the Masimo SET® 2000 have a similar method of operation and utilize the same accessories (sensors and cables, K990966 & K002574). One key difference is the device housing. The Medley SpO_2 Module is a modular system and the Masimo SET® 2000 is a stand alone pulse oximeter. This difference and other differences, as identified in this submission, are considered minor and pose no new questions or new issues regarding safety and efficacy.

Substantial equivalence

Performance data demonstrating that the Medley SpO_2 Module is equivalent to the Masimo SET® 2000 Pulse Oximeter (K990966) and that the device performs as intended has been provided. Clinical validation was performed by Masimo Corporation for the Masimo SET® 2000 Pulse Oximeter and this data serves as performance validation for the Medley SpO_2 Module.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Renée L. Fluet
ALARIS Medical Systems, Inc.
10221 Wateridge Circle
San Diego, CA 92121-2733

Re: K010966
Medley SpO_2 Module, Model 8220
Regulation Number: 870.2700
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: March 30, 2001
Received: April 2, 2001

Dear Ms. Fluet:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

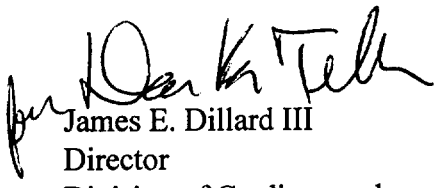
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Medley SpO_2 Module
510(k) Premarket Notification
INDICATIONS FOR USE

510(k) Number (if known): K010966

Device Name: Medley SpO_2 Module

Indications for Use:

The Medley SpO_2 Module and accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2 sensor). The Medley SpO_2 Module and accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals and hospital-type facilities.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010966

Prescription Use ✓ OR Over-The Counter Use

(Per 21 CFR 801.109)